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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,340	02/06/2002	John A. Hey	CN01383K	4276

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PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/072,340	Applicant(s) HEY ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *3-13,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the invention of Group I, claims 1, 2, and 14, in Paper No. 4 is acknowledged. The traversal is on the ground(s) that claim 15 should also be examined along with invention of Group I since the composition are recited in claim 14 and therefore should be treated as one group. This is not found persuasive because there is no claim in Group I recite a single composition of both acetylcholinesterase and H3/m2 antagonist together. Therefore, the composition is patentably distinct from the method of using the compounds concomitantly. The search fields for both inventions are therefore different. The search is not limited to patent file. The search for all inventions therefore imposes an undue burden to the Office.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of species of compound 11 on page 4 of the instant specification in Paper No. 4 and tacrine is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-16 are pending.

Claims 3-13 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

As the elected specie, compound 11 on page 4 of the instant specification, has been found to be free of prior art, the search has been extended to species. The herein

claimed method of employing Compounds 10, 12-15 has also been found o be free of prior art. The search has extended to specie of **compound 5** on page 3 in the instant specification.

Claims 1, 2, and 14 are examined insofar as they read on the elected invention and specie.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds recited in claim 2, does not reasonably provide enablement for other suitable H_3/m_2 antagonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

The claims are very broad that they cover, potentially, every compounds known to man since they encompass any compounds that can block H_3 and m_2 receptor regardless of the structure of the compounds. However, Applicants merely recite limited number of compounds. Applicant fails to set forth the criteria that define "H_3/m_2 antagonist". There is no structural or physical/chemical characteristics recited in the claims or disclosed in the instant specification. Additionally, Applicants fail to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "H_3/m_2 antagonist" examples are set forth, thereby failing to provide sufficient working examples. Please note that the compounds listed are structurally diverse. They are different structurally. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The instant claims read on all "H_3/m_2 antagonist(s)", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention because one of skilled artisan will practically have to perform certain assays on every compounds known to mankind in order to find out which compounds are useful and

which are not. The claims recited limitation "H_3/m_2 antagonist(s)" is essentially functional language. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "a dual histamine H_3 receptor antagonist/ m_2 muscarinic antagonist" in claims 1 and 14 renders the claim indefinite as to whether the invention are drawn to a dual combination of two compounds, i.e., histamine H_3 receptor antagonist and m_2 muscarinic antagonist, or one single compound possessing both H_3 receptor and m_2 muscarinic antagonistic activities.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al. (US Patent 5,883,096).

Lowe et al. teaches a method of employing Di-N-substituted piperazine compound, including compound 5 on page 3 of the instant specification as the preferred compound (when R is benzo[1,3]dioxolyl, X is SO_2, R^1 and R^{21} together form an oxo group, R^2 is a piperazine group with R^3 is H,and R^{29} is *t*-butoxycarbonyl), to treat cognition disorder and Alzheimer's disease (See the abstract and col. 6, line 25 to 64).

Lowe et al. does not expressly teach the method of treating cognition deficit by employing compound 5 specifically.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ specifically compound 5 to treat cognition deficit.

One of ordinary skill in the art would have been motivated to employ specifically compound 5 to treat cognition deficit. It is known that all of the compounds of Lowe et al. are useful to treat Alzheimer's disease and cognition disorder. Employing any preferred compounds of Lowe, such as compound 5, in the method of treating cognition deficit such as Alzheimer's disease would be reasonably expected to be effective.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al. as applied to claims 1 and 2 above, and further in view of Drug Facts and Comparisons (1999 edition, page 1731).

Lowe et al. suggests the method of employing compound 5 in a method of treating cognition deficit disorders such as Alzheimer's disease.

Lowe et al. does not expressly teach the combination of tacrine and compound 5 in a method of treating cognition deficit disorders.

Drug Facts and Comparisons teaches tacrine as useful in treating Alzheimer's disease (see page 1731).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the combination of tacrine and compound 5 in a method of treating cognition deficit disorders.

One of ordinary skill in the art would have been motivated to employ the combination of tacrine and compound 5 in a method of treating cognition deficit disorders. It is known in the art that both tacrine and compound 5 are known to be useful as treatment of Alzheimer's disease individually. Employing both agents

concomitantly for treating the very same disorder (i.e., alzheimer's disease) would be obvious (See *In re Kerkhoven* 205 USPQ 1069).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
Patent examiner
Art Unit 1617